DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Novatsep
% Mr. Gilles Audic
QA/RA Director
Espace Performance Alphasis-Batiment C1-C2
Saint Gregoire, 35769 France

December 19, 2014

Re: K142111
Trade/Device Name: ARCAD Compressive Osteosynthesis Staple, EXPRESS Compressive Osteosynthesis Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: November 17, 2014
Received: November 21, 2014

Dear Mr. Audic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142111

Device Name
ARCAD Compressive osteosynthesis staple
EXPRESS Compressive osteosynthesis staple

Indications for Use *(Describe)*
The compressive osteosynthesis staples are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

"510(k) Summary" as required by section 807.92(c)

Submitter	NOVASTEP Espace performance Alphasis Bâtiment C1-C2 35769 SAINT GREGOIRE France Phone : + 33 (0)2 99 33 86 50 Fax :+ 33 (0)9 70 29 18 95
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Preparation date	17th November, 2014

Trade name	ARCAD compressive osteosynthesis staple EXPRESS compressive osteosynthesis staple
Common Name	Staple, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories (21CFR 888.3030, product code JDR)
Regulatory class	II

Legally marketed predicate devices	510(k) number: K122113 Device name: memory metal staples, Easyclip Original applicant: STRYKER corp.
Description	Compressive osteosynthesis staples are single-use bone fixation appliances intended to be permanently implanted. ARCAD osteosynthesis staples are bipodal compression staples made of shape memory nickel titanium alloy.

Intended use	The compressive osteosynthesis staples are intended for hand and foot bone fragments osteotomy fixation and joint arthrodesis.
Comparison of the technological characteristics with the predicate device	The new devices compressive osteosynthesis staples have similar technological characteristics in terms of material (ASTM F2063-12 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants) and mechanical characteristics (ASTM F564-10 Sections A1, A2 and A4 Standard Specification and Test Methods for Metallic Bone Staples) and thus are believed to be substantially equivalent to the predicate STRYKER corp. memory metal staples, Easyclip (K122113).
Performance data	The biocompatibility evaluation for new devices compressive osteosynthesis staples was conducted in accordance with Blue Book Memorandum #G95-1 (Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing) and International Standard ISO 10993-1 (Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process) as recognized by FDA. The new devices compressive osteosynthesis staples have similar technological characteristics in terms of design and mechanical characteristics (static bending, dynamic bending and pull-out resistance) and thus are believed to be substantially equivalent to the predicate STRYKER corp. memory metal staples, Easyclip (K122113).
Indication for use	The compressive osteosynthesis staples are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.
Clinical studies	Clinical studies were not required for this submission.
Animal studies	Animal studies were not required for this submission.
Conclusion	The compressive osteosynthesis staples are substantially equivalent to their predicate devices STRYKER corp. memory metal staples, Easyclip (K122113) in terms of intended use and indications for use, material, design and function. Any minor differences between these two devices do not raise new questions of safety and effectiveness.